Citation:

Mennella JA, Garcia-Gomez PL. Sleep disturbances after acute exposure to alcohol in mothers' milk. *Alcohol.* 2001 Nov; 25(3): 153-158.

PubMed ID: 11839458

Study Design:

Non-Randomized Controlled Trial

Class:

C - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test the hypothesis that breast-fed infants will compensate for the disruptions in active sleep that occur after exposure to alcohol in their mothers' milk if their mothers then refrain from drinking alcohol.

Inclusion Criteria:

- Lactating women who had consumed at least one alcoholic beverage during lactation and who had infants with experience in drinking human milk from a bottle
- Mother–infant pairs who were not on medication that would affect sleep.

Exclusion Criteria:

Infants who do not accept the bottle.

Description of Study Protocol:

Recruitment

Ads were placed in local newspapers. Participants were also recruited from WIC centers in Philadelphia.

Design

- Within-subjects
- Each mother-infant pair was tested on two days separated by an interval of approximately one week. Mothers were instructed to refrain from drinking any alcoholic beverages on the three days before and the two days after each test day. Each mother arrived with her infant at approximately 9:30 a.m., having last fed her infant at approximately the same time on each

testing day [paired T(22df) = −1.06; P=0.30]. Testing took place in a private, carpeted room containing a portable crib for the infants. After acclimatization to the room and personnel, each mother expressed approximately 100 ml of milk, usually from both breasts by using an electric breast pump and an actigraph was placed on each infant's left leg.

Dietary Intake/Dietary Assessment Methodology

At the end of testing, mothers were interviewed and asked to complete a series of questionnaires that elicited such information as the type of advice, if any, given to them about alcohol use during lactation. They also estimated the number, types and frequency of alcoholic beverages consumed during pregnancy and lactation by completing a time-line, follow-back questionnaire.

Statistical Analysis

- Repeated measures of analysis of variance (two-by-two repeated measures ANOVAs) were conducted to determine whether there were significant differences in these measures as a function of time since exposure (zero to 3.5, 3.5 to 24 hours post-exposure) and day of the experimental period (control, alcohol)
- To allow for comparisons between between the two time periods (e.g., zero to 3.5 hours vs. 3.5 to 24 hours) for the interval data, the hourly rate for each measure was determined (e.g., minutes per hour, number of bouts per hour), with the exception of mean activity count during wakefulness, which is expressed as the average number of zero crossings of the piezoelectric beam in each time period
- Significant effects in the ANOVA were probed by paired T-tests. All summary statistics were expressed as means±SEM, and all P-values represent two-tailed tests.

Data Collection Summary:

Timing of Measurements

Each mother-infant pair was tested on two days separated by an interval of approximately one week. Mothers were instructed to refrain from drinking any alcoholic beverages on the three days before and the two days after each test day. Each mother arrived with her infant at approximately 9:30 a.m., having last fed her infant at approximately the same time on each testing day [paired T(22df) = −1.06; P=0.30].

Dependent Variables

Infants' active sleep patterns.

Independent Variables

Alcohol in mother's milk.

Description of Actual Data Sample:

- *Initial N:* 27 mother-infant pairs
- *Attrition (final N):* 23 mothers, 23 infants
- *Age:*
    - Mothers: 32.7±1.2 years
    - Infants (13 girls, 10 boys): 3.1 to 5.1 months (mean 4.0±0.1 years)
- *Location:* Philadelphia, PA.

Summary of Results:

- There was a significant interaction between the time since exposure (zero to 3.5 vs. 3.5 to 24 hours) and the experimental test day (i.e., control, alcohol) for the amount of time that infants spent in active sleep [F(1,21df) = 14.1; P=0.001]. Infants spent less time in active sleep [paired T(22df) = 2.11; P=0.05] during the hours immediately after exposure to alcohol in their mothers' milk. A decrease in active sleep was observed in 19 of the 23 infants.
- The effects of alcohol exposure on active sleep were not immediate [F(1,22df) = 8.68; P=0 .007]. There was no significant (NS) difference in the amount of time spent in active sleep during the first half of the 3.5-hour testing sessions [paired T(22df) = −0.88; P=0.39; NS]. However, infants spent significantly less time in active sleep during the second half of the test session (i.e., 1.75 to 3.5 hours), in which they were fed alcohol in mothers' milk, compared with being given mothers' milk containing no alcohol [paired T(22df) = 3.68; P=0.001].
- The data also revealed that infants compensated for such decreases when their mothers then refrained from drinking alcohol [paired T(21df) = −2.73; P=0.01]. On average, infants exhibited a 22.4%±7.0% increase in active sleep during the 20.5 hours after the test session in which they were exposed to alcohol compared with when they were exposed to mothers' milk containing no alcohol.
- There were NS interactions between time since exposure (zero to 3.5 vs. 3.5 to 24 hours) and experimental test day (i.e., control, alcohol) for any of the other variables tested (e.g., longest sleep bout, total sleep, quiet sleep, number of bouts, activity during wakefulness; all values of P>0.10)
- Mothers were apparently unaware of the differences in their infants' behaviors after alcohol exposure. That is, they were as likely as not to report that they thought that their infants consumed the alcohol-containing milk on either test day (Fisher exact probability test; P=1.0; NS).
- There were NS differences in the number of times that the infants breast fed [control vs. alcohol: 2.4±0.3 vs. 2.5±0.2; paired T(22df) = 0.42; P=0.68; not significant] or in the average amount of breast milk consumed during each feed [control vs. alcohol: 69.9±8.0 vs. 70.2±5.5 ml; paired T(22df) = 0.03; P=0.97; NS]
- As a preliminary step in determining whether maternal beliefs affected the infants' responses to alcohol exposure, an ANOVA was conducted to determine whether there were differences between infants whose mothers were encouraged to drink alcohol during lactation by a health professional (35%) and those whose mothers received no advice at all (65%). There were NS effects between these two groups on the infants' responses to alcohol for any of the sleep or activity measures studied [e.g., active sleep: F(1,20df) = 0.27; P=0.61)].

Author Conclusion:

Short-term exposure to small amounts of alcohol in mothers' milk produces distinctive changes in the infants' sleep-wake patterning.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	N/A
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes

3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	Yes
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A

6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes

8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes